Remarks

Claims 6, 7, 13, 14, 16, 18-20, 25-33, 36, 38-40 are pending, of which claims 6, 7, 13, 14, 25-33, 38 and 39 have been withdrawn from consideration. Claims 1-5, 8-12, 15, 17, 21-24, 34-35, 37 and 40 have been canceled without prejudice. Accordingly, claims 16, 18-20 and 36 are under consideration by the US Patent Office (PTO) after entry of the amendment. Claim 16 has been previously amended.

§ 112 New matter Rejection

Claim 40 is rejected for added matter. Given the cancellation of claim 40, the rejection is rendered moot.

§ 102 Rejection over Curtet

Claims 1, 8 and 34 are rejected under 35 U.S.C. § 102 over Curtet.

These claims have been canceled without prejudice, rendering the rejection moot.

§ 103 Rejection of Curtet in view of Kerč

Claims 1-5, 8-12, 15-24 and 34-37 are rejected under 35 U.S.C. § 103 as being obvious over Curtet et al (U.S. Patent No. 4,895,726) in view of Kerč et al (U.S. Patent No. 6,042,847).

Applicants respectfully traverse the rejection and respectfully submit that neither Curtet nor Kerč disclose or suggest the claimed fenofibrate tablet, with an immediate release formulation, where the required daily dosage dose is lower than 200mg, while at the same time achieving a bioavailability higher than the granule of Curtet containing 200mg..

The Examiner states in the office action at page 5, that

> *"It is familiar to one of ordinary skill in the art that such pharmaceutical compositions can be contained in various dosage forms, such as capsules, tablets, granules and the like. Such a skill is also evident from the reference of Kerč et al."*

Applicant respectfully disagrees. Applicant does not contest that tablets are known dosage forms. Applicant is of the opinion that the skilled man would not have modified Curtet into a tablet, with the expectation of an increase in bioavailability and lower inter-patient variation (see conclusive part of example 2, in relation with figure 1).

Indeed, Curtet provides for a solid dosage form, where the fenofibrate and the surfactant are co-micronized. This specific solid form would also be present in the final granules. Curtet fails to provide any motivation to modify the process. Curtet is solely concerned with co-micronization, and provides no guidance as to the relevancy of the dosage form of the drug. Hence, Curtet does not provide the required motivation to modify the granulates into a compressed tablet. Further, one skilled in the art would expect, based on the Curtet disclosure, that a compression step would make the powder of Curtet less available to the environment due to compression and thus would expect longer dissolution times, and thus a lower bioavailability. Curtet made the point that its invention is a co-micronized mixture, available as a powder. Thus Curtet teaches away from the compression step that would provide a tablet, where the solid is no longer available as a powder.

Quite unexpectedly, the invention provides a tablet, which provides superior results over Curtet, in terms of bioavailability and inter patient variation.

Applicant has provided declarations by Blouquin, (the Blouquin declaration). In the Blouquin declaration the Curtet composition is compared to the instant invention. The conclusion is that the presently claimed invention has an unexpectedly superior dissolution profile when compared to Curtet. This point is apparently not contested by the Examiner, which only indicates at page 8:

> *"The claims, as now introduced, do not encompass any requirement of a specific dissolution profile."*

The Examiner however failed to recognize that dissolution profiles can be achieved thanks to the invention. By comparing dissolution profiles, one compares what can be achieved by the invention and the prior art. The Blouquin declaration thus provides a valuable comparison between Curtet and the invention, which is a showing of the superiority of the present invention over Curtet. In addition, the specification itself contains a side-by-side comparison between Curtet and the invention; the data speak for themselves.

The Examiner further states at page 8 that

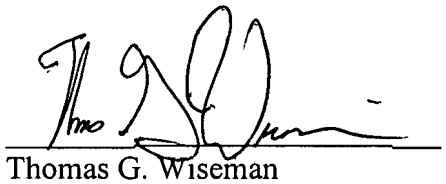
> *"Thus, the prior art formulation would also be capable of reducing inter-patient variation since similar dosage amounts as instantly claimed are disclosed."*

It is Applicant's view that the Examiner erred in this reasoning. The prior art formulation is represented by Curtet. The specification, and notably example 2 together with figure 1, provides variations. Example 2 is a side-by-side comparison between the invention and Curtet (Curtet being there referenced by its European counterpart EP-A-0330532). The data presented in figure 1 comprise standard deviation (SD), and one will notice that the SD values (in %) are about five times higher for Curtet compared to the invention. Thus, the prior art cannot be capable of reducing inter patient variation; this has been demonstrated in the specification itself. A lower inter patient variation allows for a reduction of the dose. Indeed, the dose is determined to be sure that a minimum amount of drug will be delivered. If one is looking for a final delivery of 100 units, for a high inter inter patient variation, the minimum dose will be substantially higher, say 120 units. But for a lower inter patient variation, the minimum dose will be only slightly higher, say 105 units. In the present case, having a lower inter patient variations allows a reduction in the dose of the active ingredient, while at the same being sure that a give, predetermined amount of drug will reach the site of action in any case. This could not be derived from the prior art, especially a prior art on granules (Curtet). The skilled man would not expect that a tablet form would be able to provide such a benefit, in addition to higher bioavailability.

Kerč does not fill in the gap between Curtet and the invention. As already indicated, Kerč is dedicated to sustained release. It is understandable that tablet formulations, being in a compressed stat, take a longer time to release the active in the tablet. Curtet and the invention deal with immediate release formulation, and the skilled man would not apply to Curtet a technique that is made available for sustained release. The immediate and sustained release compositions are different, remote, compositions. In any event, Kerč is silent as to potential increase in bioavailability and potential decrease in inter patient variation associated to a tablet. The skilled man would not apply the teaching of Kerč to the granules of Curtet. It is not sufficient to state that Kerč discloses tablets to apply its teaching to Curtet. The skilled man will nonetheless consider the entire teaching of Kerč; applied to Curtet the teaching of Kerč would render either Curtet or Kerč unsatisfactory for its intended purpose. However, it is a given that "the proposed modification cannot render the prior art unsatisfactory for its intended purpose". *See* MPEP at 2143.02.

An early and favorable reconsideration and allowance of claims 16, 18-20 and 36 is respectfully requested.

Respectfully submitted,



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